d.) Remarks.

Applicant has amended the specification to include a blank for the Accession Number of the deposited microorganisms which was made according to the Budapest Treaty. Applicant has also amended claims 1, 5, 14, 16, 41, 43, 44 and 49, and added new claims 51-54. Support for the amendments to the claims can be found throughout the original claims and in the specification, Figure Legends and Figures. These amendments were made to correct incorrect dependencies and other minor typographical errors. New claims 51, 52 and 53 are identical to existing claims 1, 11 and 16, respectively, except that each specifically identifies a deposited microorganism by accession number, and new claim 54 is a claim directed to a composition of the deposited microorganism. An appropriate Applicant Statement that the deposited material is identical to the material disclosed in the application is attached (37 C.F.R. § 1.804{b}). When the accession number has been assigned, Applicant will file a revised Statement and preliminary amendment incorporating the deposit number into the claims and specification. No new matter and no new issues are raised with these amendments, and their entry is respectfully requested. Currently, claims 1-19 and 21-54 are pending.

Remarks Regarding Claim Objection

Claims 5 and 41 stand objected to for certain informalities. Specifically, the Examiner asserts that the word "temperature" should be introduced with the article "a" instead of "the" in claim 4, and there should be an "are" between the words "minerals" and "phyllosilicates" in claim 41. The requested amendment was made to claim 5, but claim 41 appears to contain typographical errors. These errors were corrected by substituting the phrase "mineral substance" for the phrase "one or more clay minerals," deleting the word "phyllosilicates," and changing the dependency to claim 4. Thus, this objection is believed to be moot and Applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 112, First Paragraph

A. Claims 1-19 and 21-50 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly not enabled. Applicant respectfully traverses this rejection.

Specifically, the Examiner asserts that the starting materials are not enabled because the specification is unclear as to whether these microorganisms are available to the public.

Applicant respectfully asserts that biological materials identified in the specification by genus and/or species name were obtained from publicly available sources.

As set forth in the Manual of Patent Examining Procedure ("MPEP"):

"*In an application where the invention required access to specific biological material, an applicant could show that the biological material is accessible because it is known and readily available to the public. The concepts of "known and readily available" are considered to reflect a level of public accessibility to a necessary component of an invention disclosure that is consistent with an ability to make and use the invention. To avoid the need for a deposit on this basis, the biological material must be both known and readily available - neither concept alone is sufficient. A material may be known in the sense that its existence has been published, but is not available to those who wish to obtain that particular known biological material. Likewise, a biological material may be available in the sense that those having possession of it would make it available upon request, but no one has been informed of its existence.*

The Board of Patent Appeals and Interferences has held that a description of the precise geographic location of marine tunicates, as a biological material, used in a claimed invention was adequate to satisfy the enablement requirement of 35 U.S.C. 112. Ex Parte Rinehart, 10 USPQ2d 1719 (Bd. Pat. App. & Int. 1985). The term "readily" used in the phrase "known and readily available" is considered appropriate to define that degree of availability which would be reasonable under the circumstances. If the biological material and its natural location can be adequately described so that one skilled in the art could obtain it using ordinary skill in the art, the disclosure would appear to be sufficient to meet the enablement requirement of 35 U.S.C. 112 without a deposit so long as its degree of availability is reasonable under the circumstances.

By showing that a biological material is known and readily available or by making a deposit in accordance with these rules, applicant does not guarantee that such biological material will be available forever. Public access during the term of the patent may affect the enforceability of the patent. Although there is a public interest in the availability of a deposited biological material during and after the period of enforceability of the patent, there should not be any undue concern about continued access to the public. See 37 CFR 1.806 (the term of deposit is "at least thirty (30) years and at least five (5) years after the most recent request" for a

sample; the agreement sufficiently ensures that the deposit will be "available beyond the enforceable life of the patent"). Unless there is a reasonable basis to believe that the biological material will cease to be available during the enforceable life of the patent, current availability would satisfy the requirement. The incentives provided by the patent system should not be constrained by the mere possibility that a disclosure that was once enabling would become non-enabling over a period of time through no fault of the patentee. In re Metcalfe, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969)." (MPEP 2404.01).

As is believed to be clear, Applicant uses as starting material microorganisms and, specifically, lipid-containing microorganisms. Such microorganisms are well-known in the field and readily available from many commercial sources. This is noted in the specification at Paragraphs [0002] - [0010] and [0053] – [0059], wherein there are numerous citations to scientific publications regarding the high concentration of lipids in certain marine microorganisms and also specifically identifying those organisms. Applicant respectfully notes that, being published papers, the microorganisms disclosed are believed to be generally available to the public. Applicant also notes that a number of microorganisms are cited in the specification at paragraph [0005] that are useful according to the claims of the instant invention. These microorganisms are all generally available from microorganism repositories such as the American Type Culture Collection ("ATCC"), various universities and institution, and similar collections around the world. A link to the searchable ATCC catalog is as follows:
http://www.atcc.org/ATCCAdvancedCatalogSearch/AllCollectionSearch/tabid/454/Default.aspx.

In addition, Applicant has deposited the biological material identified in the specification as Bio30 with the German Collection of Microorganisms and Cell Cultures in accordance with the rules and regulations of the Budapest Treaty. The specification has been properly amended to include an identification of the accession number for the deposit, the date of the deposit, and the name and address of the depository (MPEP § 2411).

Thus, in view of Applicant's remarks above and the deposit of B30, the rejection of claims 1-19 and 21-50, under 35 U.S.C. § 112, first paragraph, is moot or overcome and Applicant respectfully requests that it be withdrawn.

B. Claims 1-10, 16-46 and 48-50 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly not described in the specification. Applicant respectfully traverses this rejection.

Specifically, the Examiner objects to the inclusion of the term "unextracted" in claims 1, 5 and 16. Applicant respectfully disagrees. As recited in the Manual of Patent Examining Procedure ("MPEP"):

> *"The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph. Some older cases were critical of negative limitations because they tended to define the invention in terms of what it was not, rather than pointing out the invention. Thus, the court observed that the limitation "R is an alkenyl radical other than 2-butenyl and 2,4-pentadienyl" was a negative limitation that rendered the claim indefinite because it was an attempt to claim the invention by excluding what the inventors did not invent rather than distinctly and particularly pointing out what they did invent. In re Schechter, 205 F.2d 185, 98 USPQ 144 (CCPA 1953).*
>
> *A claim which recited the limitation "said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber" in order to exclude the characteristics of the prior art product, was considered definite because each recited limitation was definite. In re Wakefield, 422 F.2d 897, 899, 904, 164 USPQ 636, 638, 641 (CCPA 1970). In addition, the court found that the negative limitation "incapable of forming a dye with said oxidized developing agent" was definite because the boundaries of the patent protection sought were clear. In re Barr, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).*
>
> *Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be*

rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. Ex parte Parks, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993)." (MPEP 2173.05(i)).

Applicant respectfully notes that the term "unextracted is believed to have a clear basis in the original disclosure to one of ordinary skill in the art from a complete reading of the specification. For example, Schemes 1, 2 and 3 each depict the production process of the invention. Each shows that the biomass remains unextracted because there are no extraction steps. In fact, to not depict an extraction step when one is present would render the production process non-enabled. Also, the claims as originally filed recited that the biomass was converted to lipid-containing particles, again indicating that the biomass remained unextracted.

Nevertheless, the Examiner's and solely to expedite prosecution, this term has been deleted without prejudice and the rejection is moot.

Thus, the rejection of claims 1-10, 16-46 and 48-50, under 35 U.S.C. § 112, first paragraph, is moot or overcome and Applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 103(a)

Claims 1-19 and 21-50 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Müeller et al. (European Journal of Pharmaceutics; "Müeller") in view of Medina et al. (Biotechnology Advances; "Medina") and Olaizola (Journal of Applied Phycology; "Olaizola"), and further in view of Kreitlow et al. (Journal of Biotechnology; "Kreitlow") and Caudales et al. (International Journal of Systematic and Evolutionary Biology, "Caudales"). Applicant respectfully traverses this rejection and incorporates all statements made in Applicant's prior responses.

The Examiner alleges that Müeller teaches "*a method of producing a pharmaceutical composition (lipid nanoparticles to use in drug delivery), applying high-pressure homogenization (and emulsification) to lipids to produce micro- and nanoparticles with a diameter of 10 nm to 10 μm (1000 nm), heating the lipids until the liquefaction, optionally adding one or more active substances or additives, mixing with a surfactant-water mixture heated to a temperature above the fatty acids melting points and unification of the two phases, preparation of pre-suspension, subjecting to one or more high pressure*

homogenization cycles, heating of the lipids and the surfactant-water mixture is omitted (cold homogenization), and active substances are adsorbed at room temperature or dispersed ...." (Office Action, pages 9-10). The examiner next asserts that Müeller does not teach cultivating a marine microorganism in the presence of clay minerals, microalgae, and homogenizing a suspension of the cultivated marine microorganism, cyanobacteria, Oscillatoriales, Chroococcales, and Nostocales. Applicant respectfully disagrees, both with the characterization of what Müeller does teach and what Müeller does not teach, and respectfully notes that Müeller in combination with any of the cited references would lead on skilled in the art in exactly the wrong direction.

Müeller is directed to the manufacture and use of highly purified lipids and discloses two basic techniques for the production of nanoparticles. First is the pressure homogenization technique (See Müeller, page 162, Section 2.1), which may involve either a hot or cold homogenization, and second is the precipitation technique (see Müeller, page 164, Section 2.4). Both begin with pure forms of lipids and the manufacturing process simply involves formation of particles. There are no microorganisms whatsoever and it appears from the process itself that Müeller goes to some significant effort to ensure that microorganisms are excluded.

Medina adds nothing to this rejection. This article is a review of the various purification techniques whereby fatty acids are extracted from fish oil, although extractions techniques from marine microorganisms are also discussed. But again, these are extracts; there is no whole-cell biomass. Also, Applicant respectfully notes that the Examiner has slightly mischaracterized a passage of Medina. In the Office Action (page 11), the Examiner states that Medina discloses "*drying and lyophilization of biomass*" (p. 527, 2nd paragraph). A full reading of this passage reveals that the authors made no such statement or implication, and the Examiner was paraphrasing. This quoted passage of Medina actually states:

> "*Extraction from freeze-dried samples has also been used. Freeze-drying breaks up the cells and turns the algal material into a loose, fine powder, making homogenization unnecessary [5]. However, direct extraction of fatty acids from wet P. tricormutum biomass (after harvesting by dentrifugation) with 96% ethanol produced only slightly lower yields (90%) than those obtained from lyophilized biomass (96%), therefore cost of extraction may be reduced by omitting lyophilization [73].*" (see Medina, page 527, second paragraph).

This passage describes an extraction technique, which is nothing like the process claimed by Applicant and, accordingly, adds nothing to the rejection. The same is true for Olaizola.

In the Office Action, the Examiner quotes Olaizola as teaching "*a process comprising cultivating marine microalgae and subjecting the biomass to high pressure homogenization*" (Abstract and p. 501 2nd column 3rd paragraph). Although in this passage, the authors do disclose how to create a biomass for processing, the process is an extraction. This passage is simply a description of how the starting material for the extract is made. In fact, the entire article is directed to extracting asaxanthin from that biomass. Thus, this reference has little to nothing to do with Applicant's claimed invention and again adds nothing to the combination of references cited against Applicant's claims.

Kreitlow is also directed to the use of purified lipid. Similar to Müeller, these authors extracted lipids from microorganisms using hexane and dichlormethane (see Kreitlow, page 62, right hand column). Applicant's respectfully note that such treatment eliminates nearly all non-lipid components of a microorganism. In direct contrast, Applicant's claimed process specifically and clearly recites that the biomass comprises one or more of a group of microorganisms. Although all of these microorganisms contain a lipid component, each is still a microorganism with all of the non-lipid components that accompany a microorganism. Further, there is no purification of the lipid component away from the non-lipid component.

Caudales is asserted in the rejection for the purpose of providing "motivation to use microalgae biomass as a source of lipid to produce nanoparticles" and thereby "teach the presence of high proportions of saturated straight chain and unsaturated straight chain fatty acids, mono- and poly-unsaturated fatty acids, and also fatty acids of different chain length in different strains of cyanobacteria (Oscillatoriales, Chroococcales, and Nostocales) (p. 1032 1st column 1st and 2nd paragraphs, 2nd column 1st paragraph, and Table 2. column 2-4)." (Office Action, page 11). Applicant agrees that most all microorganisms contain a lipid component, but disagrees that the mere presence of lipid, which are ubiquitous throughout most all living organisms, provides any sort of motivation to one skilled in the art to produce particles of marine microorganisms. Applicant's claimed invention is directed to a biomass of marine microorganisms. This would be antithetical to any disclosure of Caudales and, thus, the combination of references does not render Applicant's claims obvious.

It is the basic fact that Applicant's process and composition involves conversion of a biomass and not extraction that is both surprising and unexpected. The combination provides no hint, suggestion, teaching or motivation that one should or could use anything but purified lipids which is exactly the opposite of Applicant's process. Thus, the combination does not disclose or suggest all of the elements of Applicant's claims. Moreover, the combination expressly teaches against Applicant's claimed invention (*Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565 (Fed. Cir 1986).

In addition, Applicant respectfully notes that the inventors have achieved and successfully demonstrated surprising and unexpected results. It is well established that: "The ultimate determination of patentability must be based on consideration of the entire record...." MPEP §716.01(d), citing *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). That consideration must necessarily include Applicant's experimental results. Applicant respectfully submits that the claimed invention provides unexpectedly superior results.

Applicant respectfully notes that the authors of the combination of references would have thought Applicant's particles to be ineffective. All of the references of the combination are directed to purified extracts and, in the case of Müeller, only pure lipid material. Surprisingly, and in contrast to the results of the references, and also conventional technology, Applicant's claimed composition is both effective and has surprising advantages that are non-bactericidal in the absence of added components.

Applicant has shown in the Examples section that synergistic affects exist when the biomass of the claimed invention is coupled with known pharmaceutically active substances (e.g. see Examples 6 and 8-11). Applicant has also shown that synergistic effects are also observed when the composition of the invention is coupled with substances such as vitamin C (see Example 2 and Figure 1). Although vitamin C is not generally considered to be an antimicrobial, when couple with the composition of the invention of claim 1, the antimicrobial affects observed are synergistic. Such results would not have been predicted by any combination of the cited references. None of this is suggested from any disclosures of the combination of references. Accordingly, Applicant has demonstrated surprising and unexpected results which overcomes any assertion of obviousness.

In view of each of the reasons set forth above, the rejection must fall. Thus the rejection of claims 1-19 and 21-50, under 35 U.S.C. § 103(a), is overcome or moot and Applicant respectfully requests that it be withdrawn.

Conclusion

The application is now in condition for allowance and a Notice of Allowance is respectfully requested. If any further issues arise with regard to the prosecution of this application, the Examiner is requested to telephone the undersigned as convenient.

Should additional fees be necessary in connection with the filing of this Response, or if a petition for extension of time is required, the Commissioner is hereby authorized to charge **Deposit Account No. 14-1437 for any such fees, referencing Attorney Docket No. 9015.002.US**; and applicant hereby petitions for any needed extension of time not otherwise accounted for with this submission.

Respectfully submitted,
Novak Druce & Quigg LLP

Date: August 17, 2009

By _____
James Remenick
Registration No. 36,902

Attached: Applicant Statement under 37 C.F.R. § 1.804(b)
Certificate of Deposit

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PATENT
Attorney Docket No. 9015.002.US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gerold LUKOWSKI et al.	:	Group Art Unit: 1651
App. No.: 10/507,061	:	Examiner: Kade Ariane
Filed: August 3, 2005	:	Confirmation No.: 8844

Title: MICRO/NANOPARTICLES OBTAINED FROM LIPID-CONTAINING MARINE ORGANISMS IN PHARMACEUTICS AND COSMETICS

MAIL STOP: AMENDMENT

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

APPLICANT STATEMENT UNDER 37 C.F.R. § 1.804(b)

As set forth in 37 C.F.R. § 1.804(b) and Section 2406 Manual of Patent Examining Procedure, Applicant respectfully states that the below named person is in a position to corroborate the facts of the Deposit of Biological Material made on August 12, 2009, with regard to the above captioned patent application, and that the biological materials deposited and identified as Accession No. _____ is the biological material identified in the application as filed.

FOR APPLICANT:

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August, 2009

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DIN EN ISO 9001:2000

Ihr Zeichen/Your ref.	Unser Zeichen/Our ref.	Tel: 0531 26 16-	Datum/Date
	P155 09/VW	254 vew@dsmz.de	17.08.2009

Sehr geehrte Damen und Herren,

hiermit teilen wir Ihnen mit, dass wir am 12. August 2009 den folgenden Stamm zur Patenthinterlegung gemäß Budapester Vertrag erhalten haben:

Anabaena cylindrica B30 (Bio33)

Hinterlegerin: Enst-Moritz-Arndt-Universität Greifswald

Nach erfolgreicher Überprüfung der Lebensfähigkeit und Reinheit des Materials werden wir Ihnen die Hinterlegungsnummer übermitteln.

Dear Sir or Madam,

this is to inform you that we received on August 12, 2009, the following strain for the purposes of patent deposit according to the Budapest Treaty:

Anabaena cylindrica B30 (Bio33)

depositor: Enst-Moritz-Arndt-Universität Greifswald

The deposition number will be communicated after successful viability and purity testing.

Freundliche Grüße,

V. Weihs

Dr. Vera Weihs

DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH